REMARKS

Claims 1-10 are pending. Claims 11-41 are cancelled. Claim 1 is currently amended. The amendment is supported throughout the specification; see at least pages 6 and 10. No new matter has been added with these amendments.

All amendments and cancellations presented herein are made solely to expedite prosecution of the application without admission as to the propriety of the rejections set forth in the present Office Action and without acquiescence to the examiner's characterization of the claims or the art cited herein. Applicants respectfully reserve the right to include claims of the same or different scope as previously written in one or more continuing applications.

Examiner Interview

Applicants would like to thank the examiner for the courtesy of the interview conducted on July 7, 2010. During the interview, the examiner and the examiner's supervisor indicated that claim 35 was commensurate in scope with the unexpected results discussed. In an effort to advance prosecution, claim 1 now recites the limitation of claim 35, less any redundancies.

The examiner and Applicants' representatives also discussed the inapplicability of the obviousness type double patenting rejection to the claims in light of the claim amendments and showing of unexpected results.

Claim Rejections – 35 U.S.C. § 103(a)

Claims 1-10 stand rejected under 35 U.S.C. § 103(a) as obvious over U.S. Pat. No. 5,502,077 ("Breivik") in view of U.S. Pat. No. 4,935,243 ("Borkan") and in further view of U.S. Pat. Pub. No. 2003/0064074 ("Chang").

Applicants respectfully traverse.

I. Independent Claim 1

Reconsideration and withdrawal of the rejection of amended independent claim 1 is respectfully requested because the examiner cited references do not to disclose the claimed invention and objective evidence of non-obviousness successfully rebuts any alleged *prima facie* case of obviousness.

A. Cited References Fail to Disclose the Claimed Invention

With respect to amended independent claim 1, neither Brievik, Borkan, nor Chang, alone or in combination, disclose the claimed invention as amended. In making the assessment of differences between the prior art and the claimed subject matter, section 103 specifically requires consideration of the claimed invention "as a whole." See M.P.E.P. 2141.02 ("[T]he question

under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious."); see also KSR International Co. v. Teleflex Inc., 127 S. Ct. 1721, 1741 (2007) ("A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art."). Here, none of the references disclose a Porcine Type A soft gelatin capsule that contains an omega-3 polyunsaturated fatty acid in free acid form that

> exhibits a longer shelf life as compared to soft gelatin capsules comprising Type B gelatin, Bovine Type A gelatin or Fish Type A gelatin,
>
> wherein said soft gelatin capsules comprising Type B gelatin, Bovine Type A gelatin or Fish Type A gelatin contain a pharmaceutical formulation comprising at least one omega-3 polyunsaturated fatty acid in free acid form, and
>
> wherein the shelf life is determined by storing said soft gelatin capsule comprising Porcine Type A gelatin and said soft gelatin capsules comprising Type B gelatin, Bovine Type A gelatin or Fish Type A gelatin for 3 months at a temperature of 40°C; disintegrating each of the capsules in water at 37°C; and measuring disintegration times of each capsule to determine the shelf life of each capsule.

In particular, here, none of the references mention the limitation directed to an increased shelf life of a soft gelatin capsule.

B. Objective Evidence of Non-Obviousness

Even assuming *arguendo* that a *prima facie* case of obviousness exists in view of the Breivik, Borkan, and Chang references, Applicants hereby provide objective evidence of non-obviousness presented herewith in the Declaration of Thomas Buser Under 37 C.F.R. § 1.132.

Applicants respectfully submit that any finding of unobviousness has been rebutted for at least the reasons set forth below. In particular, "[a]ffidavits or declarations . . . containing evidence of criticality or unexpected results, commercial success, long-felt but unsolved needs, failure of others, skepticism of experts, etc., must be considered by the examiner in determining the issue of obviousness of claims for patentability under 35 U.S.C. 103." M.P.E.P. 716.01(a).

Applicants hereby submit that the claimed invention exhibits substantial unexpected results over the cited art. At least at the time of invention, one of ordinary skill in the art would have understood Type A gelatin and Type B gelatin to exhibit similar properties and have similar chemical structures. (Declaration of Thomas Buser Under 37 C.F.R. § 1.132). Moreover, the

examiner's statement that "gelatin types, between Type A and Type B are interchangeable" further evidences this belief. (Office Action, dated February 18, 2010, pg. 7 (emphasis added)).

Additionally, at least at the time the present application was filed, one of ordinary skill in the art would have understood Bovine gelatin and Porcine gelatin to be interchangeable because they exhibit similar properties. (Declaration of Thomas Buser Under 37 C.F.R. § 1.132).

It has been found with respect to the present invention that certain soft gelatin capsules can harden. (Id.). Without ascribing to a particular theory, the hardening is believed to be due to the chemical interaction between the omega-3 polyunsaturated fatty acid formulation and the gelatin itself. (Id.). Hardened capsules exhibit prolonged disintegration times and, when administered orally, may not disintegrate in the appropriate part of the digestive tract. (Id.). In other words, once a gelatin becomes hardened, soft gelatin capsules made from that gelatin may no longer be therapeutically effective. (Id.). Accordingly, the hardening effect is detrimental to the shelf life of the capsules. (Id.).

As the Declaration of Thomas Buser Under 37 C.F.R. § 1.132 states, when stored at 40°C, skin or "pellicle" forms at the interface between an omega-3 polyunsaturated fatty acid in free acid form and the following soft gelatin capsules: Bovine gelatin Type B, Bovine gelatin Type A and Fish gelatin Type A. (Id.). The formation of the skin leads to a hardening of each of these gelatins, which, thereby, prolonged their disintegration time and reduced their useful shelf life. (Id.).

Based on this information, at least at the time of invention, one of ordinary skill in the art would have expected Porcine Type A gelatin that encapsulates an omega-3 polyunsaturated fatty acid in free acid form to react in a similar manner, i.e., that skin would rapidly form at the interface between the omega-3 polyunsaturated fatty acid in free acid form and Porcine Type A gelatin, that disintegration time would be prolonged and that shelf life would be reduced. (Id.).

However, when stored at 40°C, unexpectedly no skin or "pellicle" is formed at the interface between an omega-3 polyunsaturated fatty acid in free acid form and a Porcine gelatin Type A capsule. (Id.). Disintegration time remains stable and, thereby, shelf life is prolonged. Similar results occur when the gelatins are stored at 25°C and 30°C. (Id.).

For at least the foregoing reasons, reconsideration and withdrawal of the rejection of amended independent claim 1 is respectfully requested.

II. Dependent Claims 2-10

Because amended independent claim 1 is allowable in view of the evidence and arguments presented, claims 2-10 which depend there from are also allowable for at least the same reasons.

Applicants' silence with respect to the specific rejections of the dependent claims should not be construed as a concession that the features of such claims are shown in the cited references. Rather, Applicants' silence is based on the belief that the foregoing adequately traverses the rejections of the dependent claims. Applicants hereby reserve the right to address and traverse the specific rejections of any of the dependent claims in the future.

Claim Rejections-Nonstatutory Obviousness-Type Double Patenting

Claims 1-10 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-12 and 13-17 of U.S. Pat. No. 5,792,795 ("Buser") in view of Borkan (Col. 3, lines 20-46) and in further view of Chang. Applicants respectfully traverse.

"A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s)." M.P.E.P. 804(II)(B)(1); See, e.g., In re Berg, 140 F.3d 1428 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046 (Fed. Cir. 1993); In re Longi, 759 F.2d 887 (Fed. Cir. 1985). The analysis employed in an obviousness-type double patenting rejection parallels the guidelines for analysis of a 35 U.S.C. § 103 obvious determination. M.P.E.P. 804(II)(B)(1).

For substantially the same reasons as provided by Applicants above, as applicable, reconsideration and withdrawal of the nonstatutory obviousness-type double patenting rejection of claims 1-10 is also respectfully requested. In particular, the instant claimed invention is patentably distinct over the Buser claims and, therefore, the double patenting rejecting should be withdrawn.

Conclusion

For at least these reasons, reconsideration and withdrawal of the rejections of claims 1-10 are respectfully requested. Please charge any fees due in connection with this response to Deposit Account No. 50-0310.

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Respectfully submitted,

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